



Kentucky Department for Medicaid Services Pharmacy and Therapeutics Advisory Committee Recommendations

March 18, 2016

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics Advisory Committee at the March 17, 2016 meeting.

Review of the recommendations by the Commissioner of the Cabinet for Health and Family Services and final decisions are pending.

	Description of Recommendation	P & T Vote
1	New Products to Market: Belbuca TM	Passed
	Non-prefer in PDL class: Analgesics Narcotics, Long-Acting	8 For
	Length of Authorization: 6 months, or expected duration of treatment if less than 6 months.	0 Against
	• Indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.	
	• Is there any reason that the patient cannot be switched to a preferred medication? Document the details. Acceptable reasons include	
	 Adverse reaction to preferred drugs; 	
	 Allergy to preferred drugs; and 	
	 Contraindication to preferred drugs. 	
	• Patient has inability to take oral medication OR patient has a documented clinical trial with a combination of three preferred LONG acting opiate analgesics agents.	
	Patient is 18 years or older.	
	• Refer all requests for concomitant use of long-acting narcotics to pharmacist for review.	
	Quantity Limit = 2 buccal films per day.	
2	New Products to Market: Vivlodex TM	Passed
	Non-prefer in the PDL class: NSAIDs	8 For
	Length of Authorization: 1 year	0 Against
	Indicated for management of osteoarthritis (OA) pain.	
	• Is there any reason that the patient cannot be switched to a preferred medication in the class? Document the details. Acceptable reasons include	
	 Adverse reaction to preferred drugs; 	
	 Allergy to preferred drugs; and 	
	 Contraindication to preferred drugs. 	



	Description of Recommendation	P & T Vote
	 Has the patient had a therapeutic trial and treatment failure of no less than 30 days with TWO preferred drugs in the class? Document the details. Meloxicam tablet is covered without PA; clinical reason as to why meloxicam tablet cannot be used. The safety and effectiveness of Vivlodex in pediatric patients have not been established. Quantity Limit = 1 capsule per day. 	
3	New Products to Market: Ninlaro TM	Passed
	Non-prefer in PDL class: Oncology Oral, Hematologic	8 For
	Length of Authorization: 6 months initial, 1 year renewal	0 Against
	 Indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. Safety and effectiveness have not been established in pediatric patients. 	
4	New Products to Market: Alecensa®	TABLED
_	Non-prefer in the PDL class: Oncology Oral, Lung	x For
	• Indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer who have progressed on or are intolerant to crizotinib	x Against
	 Monitor ALT, AST, and total bilirubin every 2 weeks during the first 2 months of treatment, then periodically during treatment (discontinue based on severity of drug reaction). 	
	• Ensure patient is not pregnant Quantity Limit = 2 capsules per day	
5	New Products to Market: Tagrisso TM	TABLED
	Non-prefer in PDL class: Oncology Oral, Lung	x For
	Length of Authorization: 1 year	x Against
	• Indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR TKI therapy.	
	 Prescriber needs to submit lab work documenting this mutation as detected by an FDA-approved test. 	
	• The safety and effectiveness of Tagrisso have not been established in pediatric patients.	
	Quantity Limit = 1 tablet per day.	
6	New Products to Market: Cotellic®	TABLED
	Non-prefer in PDL class: Oncology Oral, Skin	x For
	Length of Authorization: 1 year	x Against
	 Indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. 	
	Prescriber needs to submit lab work documenting this mutation as detected	



	Description of Recommendation	P & T Vote
	 by an FDA-approved test. The safety and effectiveness of Cotellic have not been established in pediatric patients. Limitation of Use: Cotellic is not indicated for treatment of patients with wild-type BRAF melanoma. 	
7	New Products to Market: Uptravi®	Passed
	Non-prefer in the PDL class: PAH Agents, Oral & Inhaled	8 For
	Length of Authorization: 6 months initial, 1 year renewal	0 Against
	• Indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH.	
	• Is there any reason that the patient cannot be switched to a preferred medication in the class? Document the details. Acceptable reasons include	
	 Adverse reaction to preferred drugs; 	
	 Allergy to preferred drugs; and 	
	 Contraindication to preferred drugs. 	
	 Has the patient had a therapeutic trial and treatment failure with ONE preferred drug in the class in the last 6 months? Document the details. 	
	 The safety and effectiveness of Uptravi in pediatric patients have not been established. 	
	Quantity Limit = 2 tablets per day for Uptravi 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,000 mcg, 1,200 mcg, 1,400 mcg, and 1,600 mcg tablets.	
	No quantity limit on the Uptravi Titration Pack.	



 New Products to Marker: Enstilar® Non-prefer in PDL class: Antipsoriatics, Topical Length of Authorization: 4 weeks Indicated for the topical treatment of plaque page and older. Is there any reason that the patient cannot be medication in the class? Document the details Adverse reaction to preferred drugs; 	e switched to a preferred
 Length of Authorization: 4 weeks Indicated for the topical treatment of plaque page and older. Is there any reason that the patient cannot be medication in the class? Document the details 	osoriasis in patients 18 years of eswitched to a preferred
 Indicated for the topical treatment of plaque page and older. Is there any reason that the patient cannot be medication in the class? Document the details 	psoriasis in patients 18 years of eswitched to a preferred
age and older.Is there any reason that the patient cannot be medication in the class? Document the details	e switched to a preferred
Is there any reason that the patient cannot be medication in the class? Document the details	<u> </u>
medication in the class? Document the details	<u> </u>
 Adverse reaction to preferred drugs; 	
Traverse reaction to preferred artigo,	
 Allergy to preferred drugs; and 	
 Contraindication to preferred drugs. 	
Has the patient had a therapeutic trial and trepreferred drug in the class? Document the det	
Minimum age restriction of 18 years of age.	
Apply Enstilar® Foam to affected area(s) once dail	ly for up to 4 weeks.
9 New Products to Market: Seebri TM Neohaler®	Passed
Non-prefer in PDL class: COPD Agents	8 For
Length of Authorization: 1 year	0 Against
Add: Dx of COPD (not indicated for use in Ast	chma)
Indicated for the long-term, maintenance trea	
patients with chronic obstructive pulmonary of	
• Is there any reason that the patient cannot be medication in the class? Document the details	_
Adverse reaction to preferred drugs;	N 11000 p table 1 case in 11102 cae
- Allergy to preferred drugs; and	
Contraindication to preferred drugs.	
Has the patient had a therapeutic trial and tree.	eatment failure with ONE
preferred drug in the same class? If so, docum	
Seebri Neohaler is not indicated for use in chi	
Seebri Neohaler in pediatric patients have not	t been established.
Quantity Limit = 2 inhalations per day	
New Products to Market: Utibron TM Neohaler®	Passed
Non-prefer in the PDL class: COPD Agents	8 For
Length of Authorization: 1 year	0 Against
Add: Dx of COPD (not indicated for use with A	
Indicated for the long-term, maintenance trea patients with chronic obstructive pulmonary of the patients.	disease (COPD).
Is there any reason that the patient cannot be medication? Document the details. Acceptable	_
 Adverse reaction to preferred drugs; 	
 Allergy to preferred drugs; and 	
 Contraindication to preferred drugs. 	
Has the patient had a therapeutic trial and trepreferred drug in the same class? If so, docum	



	Description of Recommendation	P & T Vote
	Utibron Neohaler is not indicated for use in children. The safety and efficacy	
	of Utibron Neohaler in pediatric patients have not been established.	
	Limitations of Use: Not indicated for the relief of acute bronchospasm or for the	
	treatment of asthma.	
	Quantity Limit = 2 inhalations per day	
11	New Products to Market: Viberzi®	TABLED
	Non-prefer in the PDL class: GI Motility, Chronic	8 For
	Length of Authorization: 1 year	0 Against
	• Indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D).	
	• The safety and effectiveness of Viberzi have not been established in pediatric patients.	
	Item will be "tabled" for criteria clarification.	
	Quantity Limit = 2 tablets per day.	
12	New Products to Market: Tresiba®	Passed
	Non-prefer in the PDL class: <i>Hypoglycemics, Insulins & Related</i>	8 For
	Length of Authorization: 1 year	0 Against
	Indicated to improve glycemic control in adults with diabetes mellitus.	
	Is there any reason that the patient cannot be switched to a preferred	
	medication in the class? Document the details. Acceptable reasons include	
	 Adverse reaction to preferred drugs; 	
	 Allergy to preferred drugs; and 	
	 Contraindication to preferred drugs. 	
	Has the patient had a therapeutic trial and treatment failure with ONE preferred drug in the same class? Document the details.	
	Insulin Pens	
	 Physical reasons such as dexterity problems/vision impairment; 	
	 Must be self-administered; and 	
	 NOT just for convenience. 	
	Limitations of Use: Not recommended for treating diabetic ketoacidosis.	



	Description of Recommendation	P & T Vote
13	 Antipsoriatics, Topical: DMS to select preferred agent (s) based upon economic evaluation; however, at least one unique chemical entity should be preferred. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization (PA). For any new chemical entity in the Topical Psoriasis Agents, require a PA until reviewed by the P&T Committee. 	Passed 8 For 0 Against
14	 COPD Agents: DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred. At least one combination product and tiotropium should be among the preferred products. Agents not selected as preferred will be considered non-preferred and will require PA. Continue quantity limits on agents in this class. For any new chemical entity in the COPD Agents class, require a PA until reviewed by the P&T Advisory Committee. 	Passed 8 For 0 Against
15	COPD Clinical Criteria: Length of Authorization: 1 Year Daliresp® is approvable if • Add; Has the patient's symptoms improved? If YES, then can renew. • The diagnosis is COPD AND the patient has tried/failed ONE of the following: − Ipratropium; OR − Ipratropium/Albuterol; OR − Spiriva; OR − A beta agonist (short or long acting) used on a scheduled basis Criteria to approve a non-preferred agent in this class: • Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include − Allergy to medications not requiring prior approval; − Contraindication to or drug-to-drug interaction with medications not requiring prior approval; and − History of unacceptable/toxic side effects to medications not requiring prior approval. • The requested non-preferred medication may be approved if both of the following are true: − If there has been a therapeutic failure to no less than a two-week trial of at least two preferred medications; AND − The requested medication's corresponding generic (if covered by the Commonwealth) has been attempted with multiple manufacturers (if	Passed 8 For 0 Against
	available) and failed or is contraindicated. Add: Prior to renewal of NPD agents ask: has the patient's symptoms improved? If YES, then request spirometry measurement and may approve renewal	



	Description of Recommendation	P & T Vote
	request. (newer products are all symptom based, if the symptoms haven't improved, then consider step-down therapy – removing the agent that isn't working).	
16	 GI Motility, Chronic: DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. Agents not selected as preferred will be considered non-preferred and will require PA. For any new chemical entity in the GI Motility, Chronic class, require a PA until reviewed by the P&T Committee. 	Passed 8 For 0 Against
17	 Hypoglycemics alpha-glucosidase inhibitors: DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. Agents not selected as preferred will be considered non-preferred and will require PA. For any new chemical entity in the Alpha-Glucosidase Inhibitor class, require a PA until reviewed by the P&T Advisory Committee. 	Passed 8 For 0 Against
18	 Hypoglycemics Amylin Analogues: DMS to select preferred agent (s) based on economic evaluation. Allow for use of pramlintide with active insulin therapy only. Agents not selected as preferred will be considered non-preferred and will require PA. For any new chemical entity in the Amylin Analogue class, require a PA until reviewed by the P&T Advisory Committee. 	Passed 8 For 0 Against
19	 Hypoglycemics DPP4 Inhibitors: DMS to select preferred agent (s) based on economic evaluation; however, at least one single entity agent should be preferred. Agents not selected as preferred will be considered non-preferred and will require PA. For any new chemical entity in the DPP4-Inhibitors class, require a PA until reviewed by the P&T Advisory Committee. 	Passed 8 For 0 Against



	Description of Recommendation	P & T Vote
20	 Hypoglycemics GLP-1 Receptor Agonists: DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. Continue to require PA for all agents in this class to ensure appropriate utilization. For any new chemical entity in the GLP-1 Receptor Agonists class, require a PA until reviewed by the P&T Advisory Committee. 	Passed 8 For 0 Against
21	 Hypoglycemics Insulins and Related: DMS to select preferred agent (s) based upon economic evaluation; however, at least one insulin per class (bolus, basal, premixed, rapid-acting, biphasic, and long-acting) should be preferred. Agents not selected as preferred will be considered non-preferred and will require PA. For any new chemical entity in the Injectable Insulins class, require a PA until reviewed by the P & T Advisory Committee. 	Passed 8 For 0 Against
22	 Hypoglycemics Meglitinides: DMS to select preferred agent (s) based on economic evaluation; however, at least one single entity agent should be preferred. Agents not selected as preferred will be considered non-preferred and will require PA. For any new chemical entity in the Meglitinides class, require a PA until reviewed by the P&T Advisory Committee. 	Passed 8 For 0 Against
23	 Hypoglycemics Metformins: DMS to select preferred agent (s) based on economic evaluation; however, at least metformin should be preferred. Agents not selected as preferred will be considered non-preferred and will require PA. For any new chemical entity in the Hypoglycemics, Metformins class, require a PA until reviewed by the P&T Advisory Committee. 	Passed 8 For 0 Against
24	 Hypoglycemics SGLT2s: DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. Agents not selected as preferred will be considered non-preferred and will require PA. For any new chemical entity in the Diabetes: SGLT2 Inhibitors class, require a PA until reviewed by the P&T Advisory Committee. 	Passed 7 For 1 Abstain 0 Against
25	 Hypoglycemics Sulfonylureas: DMS to select preferred agent (s) based on economic evaluation; however, at least two unique second generation sulfonylureas should be preferred. Agents not selected as preferred will be considered non-preferred and will require PA. For any new chemical entity in the Sulfonylureas and Combination class, require a PA until reviewed by the P&T Advisory Committee. 	Passed 8 For 0 Against



	Description of Recommendation	P & T Vote
26	Hypoglycemics, TZDs:	Passed
	DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred.	8 For 0 Against
	Continue quantity limits based on maximum recommended dose.	
	Agents not selected as preferred will be considered non-preferred and will require PA.	
	• For any new chemical entity in the Diabetes: Thiazolidinediones class, require a PA until reviewed by the P&T Advisory Committee.	
27	Hypoglycemics Clinical Criteria Review INSULINS:	Passed 8 For
	Length of Authorization: 1 Year	0 Against
	• Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:	
	 Allergy to medications not requiring prior approval; 	
	 Contraindication to or drug-to-drug interaction with medications not requiring prior approval; and 	
	 History of unacceptable/toxic side effects to medications not requiring prior approval. 	
	• The requested non-preferred medication may be approved if both of the following are true:	
	 If there has been a therapeutic failure of at least one preferred medication within the last 90 days, within the same class; AND 	
	 The requested medication's corresponding generic (if covered by the Commonwealth) has been attempted with multiple manufacturers (if available) and failed or is contraindicated. 	
	For Pens and Cartridges that are non-preferred:	
	Patient is 15 years of age and under; OR	
	• Patients or active care-givers that are unable to manipulate vials/syringes due to issues related to poor eyesight, dexterity, or comprehension can be approved for pens/cartridges.	
28	Hypoglycemics Clinical Criteria Review	Passed
	BYETTA & BYDUREON:	8 For
	Preferred GLP-1 Agonists (Byetta & Bydureon) will be approved if metformin, a sulfonylurea, insulin, a DDP-4 inhibitor, OR a thiazolidinedione (TZD) is seen in history within the past 90 days.	0 Against
29	Hypoglycemics Clinical Criteria Review	Passed
	SYMLIN:	8 For
	A trial of ANY insulin in the last 90 days will suffice for approval on this medication	0 Against
30	Hypoglycemics Clinical Criteria Review	Passed
	ORAL AGENTS: (not otherwise addressed through other criteria)	8 For
	Length of Authorization: 1 Year • Is there any reason the patient cannot be changed to a medication not	0 Against
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	Description of Recommendation	P & T Vote
	 requiring prior approval? Acceptable reasons include Allergy to medications not requiring prior approval; Contraindication to or drug-to-drug interaction with medications not requiring prior approval; and History of unacceptable/toxic side effects to medications not requiring prior approval. The requested non-preferred medication may be approved if both of the following are true: If there has been a therapeutic failure to no less than a one-month of at least two preferred medications (unless only 1 available); AND The requested medication's corresponding generic (if covered by the state) has been attempted with multiple manufacturers (if available) and failed or is contraindicated. 	
31	Hypoglycemics Clinical Criteria Review SGLT2s: SGLT2 Inhibitors should only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin	Passed 8 For 0 Against
32	 Hypoglycemics Clinical Criteria Review PRANDIMET: Diagnosis is Diabetes Mellitus Type 2 AND patient is currently treated with a meglitinide and metformin; OR Patient is inadequately controlled on a meglitinide alone or metformin alone. 	Passed 8 For 0 Against
33	Hypoglycemics Clinical Criteria Review DPP4 INHIBITORS: Length of Authorization: 1 Year A preferred DPP-4 Inhibitor will be approved for one of the following reasons: • Metformin, insulin, sulfonylurea, or a thiazolidinedione is seen in history within the past 90 days; OR • The patient has a diagnosis of Chronic Renal Insufficiency or Chronic Renal Failure (ICD-10 = 585.9). Approval criteria for a non-preferred DPP4 Inhibitor: • Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include: - Allergy to medications not requiring prior approval; - Contraindication to or drug-to-drug interaction with medications not requiring prior approval; and - History of unacceptable/toxic side effects to medications not requiring prior approval. • The requested non-preferred medication may be approved if both of the following are true: - If there has been a therapeutic failure of at least two preferred medications; AND	Passed 8 For 0 Against
	If there has been a therapeutic failure of at least two preferred	



Description of Recommendation	P & T Vote
available) and failed or is contraindicated.	

